

Region 3 EtO Communication and Media Plan

Issue

EPA conducted a risk analysis as part of an upcoming Clean Air Act proposal to address emissions of air toxics about 25 commercial sterilizers that emit ethylene oxide at levels causing elevated long-term cancer risks in the communities in which they are located. EtO is used to sterilize about 50% of all medical devices in the US. Many commercial sterilization facilities are located near residences. In general, about half of the high-risk facilities are in communities that have greater percentages of residents of color and low-income residents than the national average. In addition, the closer a facility is to a population, the higher the cancer risk will be.

In Region 3, there are eight high-risk facilities. Although, two facilities are slightly under the benchmark of 100/million, but when rounded falls within the benchmark. In addition, one facility, B Braun has since fallen below the benchmark, but outreach will be conducted as mandated in the Inspector General's report.

List of Region 3 Commercial Sterilizers Where Risk was/is at or above 100/Million

STATE	FACILITY NAME	LOCATION
PA	American Contract Systems	Zelienople
PA	B Braun Medical Inc.	Allentown
PA	Cosmed Group LLC	Erie
MD	Elite Spice, Inc.	Hanover
MD	Elite Spice, Inc.	Jessup
MD	Fuchs North American	Hampstead
MD	Trinity Sterile, Inc.	Salisbury
VA	Sterilization Services of Virginia	Richmond

Agency/Regional Action

To inform and engage with the affected communities, EPA is reaching out to state, tribal and local governments, and stakeholders to share up-to-date information and address the risks posed by air emissions of ethylene oxide (EtO) from commercial sterilizers and other industrial facilities. Long-term exposure to high concentrations of EtO can increase the lifetime risk of getting cancer.

EPA has been working with federal partners, communities, states, Tribes, and other stakeholders to reduce the risks posed by EtO since 2018. Recently, EPA collected information in support of a Clean Air Act regulation to control EtO from commercial sterilizers. EPA used updated EtO emissions information from commercial sterilizers to estimate the increased risk of getting cancer related to the EtO emitted from almost 100 commercial sterilizers. The agency found elevated risks at about 25 of those sterilizers. The agency is sharing this risk information so that states, Tribes, communities, and the industry can engage fully in promoting

actions to reduce risk from EtO and in the development of EPA's emissions reduction rules, which will rely on already proven and available air pollution controls.

Key Messages

- Ethylene oxide (EtO) is a significant contributor to air toxics risk and is a major priority for the Agency.
- Working with its state, local and Tribal partners, the agency is engaging with communities where data and analysis indicate that lifetime cancer risks from commercial sterilizer EtO emissions are highest.
- This outreach to communities impacted by risk from EtO is meant to inform them and include them in steps to reduce those risks.
- Partnership with communities, facilities, and state, local, and Tribal government is key to reducing risk from air toxics.
- EPA is committed to letting science, data, and evidence drive EPA decision-making processes on environmental health risks.
- Under the leadership of President Biden's Administration and Administrator Regan, the EPA has reinvigorated its commitment to protect public health from toxic air emissions from industrial facilities – especially in communities that have already suffered disproportionately from air pollution and other environmental burdens for far too long.
- We are on track to improve our data on emissions of toxic air pollution, communicate risks to the public, develop regulatory solutions, and deliver pollution reductions for American communities.

Roll Out Timeline (R3 actions are in red)

[LINK Excel.Sheet.12

[https://usepa.sharepoint.com/sites/EtOCoordination/Shared%20Documents/Outreach%20Materials/Timeline%20\(Do%20Not%20Edit\)/EtO%20Timeline%20-%20Preproposal%20Outreach.xlsx](https://usepa.sharepoint.com/sites/EtOCoordination/Shared%20Documents/Outreach%20Materials/Timeline%20(Do%20Not%20Edit)/EtO%20Timeline%20-%20Preproposal%20Outreach.xlsx)
forPlan!R1C1:R25C4 \a \f 5 \h * MERGEFORMAT]

Pre-August 3 Desk Statement for Regions- DRAFT – Not Final – Still Under Review – Do Not Use

In the coming weeks, the U.S. Environmental Protection Agency will be sharing its latest available information on ethylene oxide (EtO) emissions at commercial sterilizer facilities, and engaging with communities located near these facilities, as part of an effort to develop more protective Clean Air Act standards for these emissions. EPA continues to receive additional EtO emissions information which we are using to finalize the data we are going to release in a few weeks. We are also continuing to work with state, local and Tribal governments, communities, and companies to identify near-term solutions to reduce EtO pollution as quickly as possible. EPA is committed to keeping the public and affected communities informed about EtO emissions and health risks, and to taking swift action to reduce these emissions to health-protective levels.

Background

EtO is a colorless and flammable gas. It is typically odorless in the concentrations found outside of facilities or in communities. EtO is used in making other chemicals and products like antifreeze and plastic bottles, as well as to sterilize medical equipment and sometimes spices.

FDA has noted that EtO is used to sterilize over half of the medical equipment for use in the United States. EtO has been used to sterilize medical equipment since the late 1950s.

For more information, please visit <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide>

Post-August 3 Desk Statement for Regions- DRAFT – Not Final – Still Under Review – Do Not Use

The U.S. Environmental Protection Agency is committed to reducing health risks from pollution created by air toxics and is working to update and strengthen Clean Air Act standards for commercial sterilizers to achieve that goal. As part of that process, EPA is reaching out to state, local and Tribal governments, communities facing the highest risks, other interested parties, and industry to share information and hear input on protecting health and reducing toxic emissions from these facilities.

Ethylene oxide (EtO) is the pollutant causing health risk near commercial sterilizers. These facilities do not pose an immediate public safety concern. However, a lifetime of exposure to EtO emissions could lead to long-term health impacts at the current levels observed at some of these facilities.

As part of the upcoming proposal to further reduce toxic emissions of EtO from commercial sterilizers, EPA recently conducted a risk assessment that indicates EtO emitted into the air from this facility is likely to pose an elevated lifetime health risk for nearby residents.

Over the coming weeks, EPA will be sharing the EtO emissions and risk information with impacted communities. The agency aims to improve the public understanding of the risk; to help states, Tribes, communities and the industry reduce risk from EtO in the near-term; and to hear input as the agency continues to develop regulations to reduce air pollution from commercial sterilizers.

EPA's Region X office is in the process of contacting communities where EPA's analysis indicates that EtO risks are unacceptably high.

Background

EtO is a colorless and flammable gas. It is typically odorless in the concentrations found outside of facilities or in communities. EtO is used as a "building block" to make other chemicals and products like antifreeze and plastic bottles, as well as to sterilize medical equipment and sometimes spices.

FDA has noted that EtO is used to sterilize over half of the medical equipment that is sterilized for use in the United States. EtO has been used to sterilize medical equipment since the late 1950s.

For more information, please visit [HYPERLINK "<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide>"]

Talking Points DRAFT – Not Final – Still Under Review – Do Not Use

- I wanted you to be aware that EPA is conducting outreach in _____ related to levels of ethylene oxide from [facility] in [town].
- EPA recently conducted a risk assessment that indicates EtO emitted into the air from this facility is likely to pose elevated lifetime cancer risk for nearby residents.
- The facility does not pose an immediate risk; however EPA is concerned about the long-term health implications from exposure to this chemical.
- We are scheduling a public meeting to provide information about this chemical and the facility and to answer questions from community members.
- EPA is developing Clean Air Act regulations to further reduce EtO emissions from commercial sterilizers.
- EPA is developing proposed mitigation measures that will reduce risks to workers and those who are exposed to other ways by setting limits on the use of EtO under federal pesticide law
- At the same time, we are working with state, local, Tribal governments, communities, and the companies to identify near-term solutions to reduce EtO pollution as quickly as possible.
- Date and time of community meeting/website for more information/regional contact.

Press Release DRAFT – Not Final – Still Under Review – Do Not Use

EPA Launches Public Outreach to Engage Communities About New Ethylene Oxide Risk Information

Contact: EPA Press Office, [[HYPERLINK "mailto:press@epa.gov"](mailto:press@epa.gov)]

WASHINGTON (XX, XX 2022) – Today, the US Environmental Protection Agency (EPA) announced its plans to engage and inform communities, states, Tribes, and stakeholders about up-to-date information on the risks posed by air emissions of ethylene oxide (EtO) from commercial sterilizers, as well as EPA’s efforts to address these risks. EPA is releasing new information on specific facilities where risk levels are the highest and is encouraging impacted communities to participate in a series of public engagements to learn more.

These facilities do not pose an immediate public safety concern. However, the concern is that a lifetime of exposure to EtO emissions could lead to long-term health impacts if these facilities continue to emit at the current levels.

“Today, EPA is taking action to ensure communities are informed and engaged in our efforts to address ethylene oxide, a potent air toxic posing serious health risks with long-term exposure,” **said EPA Administrator Michael S. Regan**. “Under my watch, EPA will do everything we can to share critical information on exposure risk to the people who need and deserve this information, and to take action to protect communities from pollution.”

EPA is taking a phased outreach approach to engage the American public on this issue. This includes detailed web material with risk information for communities and a national public webinar taking place on August 10 from 8:00 to 9:30PM Eastern. EPA will be following this national level outreach with community specific engagements starting with communities where the risk is the highest.

To register for the national public webinar and learn more about upcoming community meetings. (need hyperlink)

Since 2018, EPA has been working with federal partners, communities, states, Tribes, and stakeholders to reduce the risks posed by EtO exposure. Recently, EPA collected information in support of a Clean Air Act regulation to control EtO from commercial sterilizers. EPA used updated EtO emissions information from commercial sterilizers to estimate the increased risk of cancer related to the EtO emitted from almost 100 commercial sterilizers. The agency found elevated risks at 25 of those sterilizers. Long-term exposure to high concentrations of EtO can increase the lifetime risk of getting cancer.

The agency is sharing this risk information so that communities located near commercial sterilizers, and members of the public concerned about EtO exposure, have up to date information about emissions and health risks from EtO and can make informed decisions. EPA expects to propose an air pollution regulation later this year to address EtO emissions at commercial sterilizers. This regulation will rely on the best available science and proven air pollution controls. At the same time, we are working with state and local governments, facilities, and other partners to s to identify and implement near-term steps to reduce this pollution as soon as possible.

To view the list of sterilizers with elevated risk (hyperlink webpage)

EPA will hold a virtual meeting for the public on INSERT DATE. Community members living near high-risk commercial sterilizers are especially encouraged to attend and participate.

In addition to the initiative announced today, EPA has taken significant action to address EtO and advance critical EtO research. These actions include:

1. Reviewing Clean Air Act regulations for industries that emit EtO into the air, particularly rules to control air toxic emissions from commercial sterilizers and facilities that manufacture chemicals
2. Working with state and local air agencies to reduce EtO emissions
3. [HYPERLINK "<https://www.epa.gov/newsreleases/epa-expands-tri-reporting-requirements-ethylene-oxide-and-ethylene-glycol-requiring>" \ | ":~:text=WASHINGTON%20(Dec.,ethylene%20oxide%20(EtO)%20releases."]
4. [HYPERLINK "<https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto>"] how EtO is used within sterilization facilities with the goal of reducing risks to workers who handle EtO and those who are exposed in other ways
5. Conducting research to better understand and measure EtO

About Ethylene oxide

Ethylene oxide, a colorless, odorless gas, is used to sterilize devices that cannot be sterilized using steam or radiation, such as some medical and dental equipment. According to the Food and Drug Administration, EtO is currently used to treat approximately 50% of sterile medical devices, about 20 billion medical devices annually.

July 19, 2022
DRAFT Internal Use Only
Do not distribute

EtO is also produced in large volumes at some chemical manufacturing facilities. In the U.S., it is primarily used to make other chemicals that are used to make a range of products, including antifreeze, textiles, plastics, detergents, and adhesives. EtO is also used to sterilize some food products and spices.

To stay up to date on the latest activities and actions related to EtO, please visit [HYPERLINK "https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-eto-explained" \h].

Q&A

EtO Topic

- External QAs – comments from other OSHA, ATSDR and FDA being incorporated. Posted on web on a rolling basis
- EPA Internal QAs – undergoing final review

Internal Process

- **When and how is EPA reaching out to local public health officials?**
 - A few days in advance of the public announcement, EPA regional offices will be sending an email to local public health officials alerting them that there is a commercial sterilizer in their community that is elevating the cancer risk for residents. The notification will share website resources for general EtO information and [[HYPERLINK "mailto:eto@epa.gov"](mailto:eto@epa.gov)] as mechanism for contacting EPA.
 - Goal: Provide local public health official an opportunity to prepare for questions from their local residents and elected officials about the health impacts of ethylene oxide from commercial sterilizers.
- **Why didn't EPA reach out earlier?**
 - EPA is reaching out with this information very early in the process as the agency is developing a proposed rule. The reason EPA is reaching out at this stage is because we feel it's important for communities and facilities to have this information now.
 - EPA has continued to receive additional information in recent months and is releasing the latest analysis.
- **When and how is EPA reaching out to state public health officials?**
 - EPA invited state public health officials to join our EtO overview webinars on May 5 and May 12, 2022 via their trade association.
 - In addition, state public health officials will be invited to a briefing around the time of the announcement.
 - Goal: Provide information about EPA's upcoming information release and a preview of EPA's risk communications plan.
- **What outreach has EPA done with state environmental agencies?**
 - Since 2018, EPA has been working with state environmental regulators to address emissions of ethylene oxide and the potential health risks associated with EtO.
 - Goal: Ensure that the emissions information and other technical inputs are understood in relation to EPA's risk assessment of commercial sterilizers. Partner with states to get early

reductions of EtO emissions while continuing to maintain a safe supply of medical devices in the US. Share information about risk communication and plans for meeting with communities.

- **What coordination has EPA done with other federal agencies?**

- EPA, FDA, OSHA and ATSDR have been part of an interagency workgroup about ethylene oxide since February 2020. The workgroup includes senior career leaders and technical experts.
 - As part of these interagency meetings, EPA and OSHA have been coordinating on worker protections and language for an upcoming EPA action related to EtO's use as a pesticide.
- EPA has shared draft documents for the upcoming announcement as well as the list of facilities causing high risk in about 25 communities across the country as of June/July 2022.
- On July 15, EPA will provide training about risk communication and EtO for staff from federal agencies – HQ and regional offices.
- A briefing for federal partners on the risk communication plan will be held with FDA, OSHA, and ATSDR in advance of the announcement.
- Goal: Seamless coordination and information sharing about the importance of the medical device supply chain and the need to get reductions of EtO emissions from commercial sterilizers and other sources as quickly as possible in those communities where this air toxic is elevating the risk of people getting cancer. Also, share risk communication strategies and provide the public with consistent information.

- **When and how is EPA communicating with Mayors and Local Elected Officials?**

- Mayors and local officials representing the approximately 25 communities with elevated cancer risk caused by air emissions of EtO will be contacted by EPA regional offices in advance of the public announcement.
- EPA HQ will provide talking points, web resources with health information, and a basic background for EPA regional offices to give elected officials a "heads up," including that EPA will be posting a map of the area surrounding the facility that will include cancer risk information in the coming days.
- EPA will invite the local officials to the national webinar the following week.

- **When and how is EPA communicating with Governors?**

- In addition to contacts through state agencies, EPA will provide a high-level briefing for Governors' staff in advance of the announcement (likely August 1st.)

- **How and when has EPA communicated with the commercial sterilizer industry?**

- EPA has held scores of calls with the trade associations and individual commercial sterilizing facilities. Highlights of those interactions over the past 4 years include:
- Interactions around the Information Collection Requests made by EPA under the Clean Air Act to that requires industry to submit information about air toxic emissions from facilities.

July 19, 2022

DRAFT Internal Use Only

Do not distribute

- Review of industry comments submitted in response to EPA's December 2019 Advance Notice of Proposed Rulemaking.
- Individual meetings with facilities to discuss emission reduction possibilities, that first came to light in EPA's 2018 National Air Toxic Assessment (now AirToxScreen).
- Meetings and document exchanges around the 2016 IRIS assessment where EPA explained the science behind the updated cancer value.
- Visits and inspections of commercial sterilizers.
- Staff to staff meetings and teleconferences sharing information about concerns and supply chain issues.
- Participated in industry-sponsored conferences and workshops.
- Conversations between EPA leadership and industry representatives.

*****[LINK Excel.Sheet.12
<https://usepa.sharepoint.com/sites/EtOCoordination/Shared%20Documents/Outreach%20Materials/Timeline/EtO%20Timeline%20-%20Preproposal%20Outreach.xlsx> forPlan!R1C1:R22C4 \a \f 4 \h *
MERGEFORMAT]

HQ Roll Out Timeline (Tick Tock)

[LINK Excel.Sheet.12 "[https://usepa.sharepoint.com/sites/EtOCoordination/Shared Documents/Outreach Materials/Timeline \(Do Not Edit\)/EtO Timeline - Preproposal Outreach.xlsx](https://usepa.sharepoint.com/sites/EtOCoordination/Shared Documents/Outreach Materials/Timeline (Do Not Edit)/EtO Timeline - Preproposal Outreach.xlsx)" forPlan!R1C1:R25C4 \a \f 5 \h * MERGEFORMAT][LINK Excel.Sheet.12
<https://usepa.sharepoint.com/sites/EtOCoordination/Shared%20Documents/Outreach%20Materials/Timeline/EtO%20Timeline%20-%20Preproposal%20Outreach.xlsx> forPlan!R1C1:R22C4 \a \f 4 \h *
MERGEFORMAT]

Hill Outreach

- EPA will brief Hill the day prior to release.
 - Staff of the Congressional EtO Task Force, EPW and HEC committee staff
 - Staff from personal offices with commercial sterilizers identified by EPA's risk assessment has having commercial sterilizers causing elevated risk for residents surrounding the facility